

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

**IN RE: ZOLOFT
(SERTRALINE HYDROCHLORIDE)
PRODUCTS LIABILITY LITIGATION**

***THIS DOCUMENT RELATES TO ALL
ACTIONS***

§ **MDL NO. 2342**
§
§ **12-MD-2342**
§
§ **HON. CYNTHIA M. RUFÉ**
§
§

**MOTION TO AMEND PRETRIAL ORDER NOS. 39, 44, AND 56
TO EXTEND TRIAL SCHEDULE**

The parties have conferred and have been unable to reach an agreement, accordingly Defendants Pfizer Inc., including its former division J.B. Roerig & Co., Pfizer International LLC, and Greenstone LLC (collectively, “Defendants”) respectfully move the Court to amend Pretrial Order Nos. 39, 44, and 56, with respect to the remaining schedule through trial in order to extend the schedule to allow the parties to complete case-specific discovery in the Discovery Group cases. For the reasons set forth in detail in the accompanying Memorandum, Defendants respectfully request that the Court amend the schedule as set forth below:

Deadline	Current Date	Requested Date
Designation of cases for the Trial Pool from the Initial Discovery Pool.	April 30, 2014	June 11, 2014
Parties to provide Court a list of the Trial Pool Cases, along with a short summary of each Plaintiff’s Case.	May 5, 2014	June 16, 2014

Plaintiffs' additional non-causation expert reports and all case-specific expert reports for Trial Pool Cases shall be served.	May 30, 2014	July 11, 2014
Pfizer Defendants' additional generic non-causation expert reports and all case specific expert reports for Trial Pool Cases shall be served.	June 30, 2014	August 11, 2014
Generic and case specific expert discovery for Trial Pool Cases shall be completed.	August 15, 2014	September 26, 2014
<i>Daubert</i> motions and dispositive motions related to the Trial Pool Cases shall be due.	September 8, 2014	October 20, 2014
Responses to <i>Daubert</i> motions and dispositive motions related to the Trial Pool Cases shall be due.	September 22, 2014	November 3, 2014
Replies in support of <i>Daubert</i> motions and dispositive motions related to the Trial Pool Cases shall be due.	September 29, 2014	November 10, 2014

Motions in limine and motions concerning any documents as to which no agreement to admit has been reached shall be due.	October 14, 2014	November 25, 2014
Responses to motions in limine and motions concerning any documents as to which no agreement to admit has been reached shall be due.	October 20, 2014	December 1, 2014
Replies in support of motions in limine and motions concerning any documents as to which no agreement to admit has been reached shall be due.	October 27, 2014	December 8, 2014
Jury questionnaires distributed and jury selected.	October 28-29, 2014	December 9-10, 2014
Final pre-trial conference (including ruling on motions in limine and document issues, to the extent not reserved until trial).	October 30, 2014	December 11, 2014
First trial begins; opening statements and start of testimony.	November 3, 2014	January 7, 2015
Trial testimony continues.	November 4-10, 2014	January 8-14, 2015
Trial testimony continues.	November 11-21, 2014	January 15-27, 2015

Closing arguments and jury instructions; start of jury deliberations.	November 24, 2014	January 28, 2015
Jury deliberations continue.	November 25, 2014	January 29, 2015

WHEREFORE, Defendants respectfully request that Court enter the above proposed schedule.

Dated: New York, New York
April 24, 2014

Respectfully submitted,

/s/ Mark S. Cheffo

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*Attorneys for Defendants Pfizer Inc.,
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Co., Pfizer International LLC, and
Greenstone LLC*

CERTIFICATE OF SERVICE

I hereby certify that on April 24, 2014, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which shall send electronic notification of such filing to all CM/ECF participants.

Dated: New York, New York
April 24, 2014

/s/ Mark S. Cheffo

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

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**DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION TO AMEND
PRETRIAL ORDER NOS. 39, 44, AND 56 TO EXTEND TRIAL SCHEDULE**

Pfizer Inc., including its former division J.B. Roerig & Co., Pfizer International LLC, and Greenstone LLC (collectively, "Defendants") respectfully submit this memorandum in support of their motion to amend Pretrial Order ("PTO") Nos. 39, 44, and 56 in order to briefly extend the current trial schedule.

PRELIMINARY STATEMENT

The parties in this litigation have followed an aggressive jointly agreed upon schedule and have made considerable progress to date. Millions of pages of documents have been produced, numerous depositions have been taken on both sides, and general causation arguments have been briefed and heard by this Court, with final briefing due next week. Unfortunately, there remains a critical disparity in the progress of core case-specific discovery in the Discovery Group cases, from which the Trial Pool is to be selected. Specifically, the threshold discovery in Defendants' Discovery Group case selections, including the collection of medical records, production of Plaintiffs' documents, and the depositions of Plaintiffs, prescribing physicians, and treating physicians, is significantly less advanced than the same discovery in Plaintiffs' Discovery Group case selections. This disparity is primarily the result of: 1) Plaintiffs' dismissals of Defendants' Discovery Group cases, requiring the need for replacement selections (with 14 of Defendants' selections dismissed, including several cases dismissed as late as December 2013 and January 2014), resulting in much later starts on threshold discovery in Defendants' selections as compared to Plaintiffs' selections (all of which

were designated more than a year ago, in March 2013); and 2) the unexpected cessation of records collection for nearly three months due to the transition from Medical Research Consultants to RecordTrak as the designated vendor for the collection of medical and other third-party records. These two circumstances have impeded Defendants' ability to obtain key records and other documents in the Discovery Group cases, including documents necessary to meaningfully depose Plaintiffs and their healthcare providers and to properly evaluate the cases for consideration as potential Trial Pool selections.

As a result, Defendants believe the parties lack sufficient information to adequately select representative cases for the Trial Pool and that the Court will similarly lack sufficient information to choose the first cases for trial. Accordingly, as set forth in further detail below, in order to give the parties additional time to complete case-specific discovery and select cases for the Trial Pool, Defendants respectfully request a short extension of approximately six to eight weeks in the current schedule through trial, with a trial starting in early January.

ARGUMENT

1. There is a Significant Disparity in Case Specific Discovery

As the following examples make clear, there is a significant disparity in case-specific discovery between Plaintiffs' Discovery Group selections and Defendants' selections:

- **Medical Records:** Of approximately 96,000 pages of medical records collected to date, approximately 76,500 pages, or 80%, are from Plaintiffs' selections and 19,500, or 20%, are from Defendants' selections. Defendants understand from RecordTrak that there are currently records for dozens of providers that were recently collected and are not yet available to Defendants because they are subject to Plaintiffs' counsel's exclusive review for 20 days, the majority of which are in Defendants' Discovery Group cases. In addition, Defendants understand there to be numerous additional providers for whom records remain outstanding, again, the majority of which are in Defendants' Discovery Group cases.
- **Other Documents:** In addition, Plaintiffs' documents, including medical records in their possession, emails, photographs, and other documents required to be produced by agreement or the Special Master's Report and Recommendation No. 5 (adopted by the

Court in PTO 40) have not been provided in many of Defendants' selections until very recently, sometimes at or just prior to a Plaintiff's or physician's deposition.¹

- **Prescriber and other Healthcare Provider Depositions:** For efficiency and other reasons, the parties have not proceeded with physician depositions until after the Mother Plaintiff is deposed. In Plaintiffs' selections, the majority of the Mother Plaintiffs were deposed by February 2014 because the parties agreed there were generally adequate records available to proceed. By contrast, in Defendants' selections, the majority of the Mother Plaintiffs were not deposed until March and April 2014. As a result of records and scheduling issues, including physicians' busy schedules and the need to take the Mother Plaintiff's deposition first, the parties have not yet taken prescriber depositions in 10 of Defendants' selections (*Asphalt, Casl, Conn, Dillard, Keel, Phelps, Potts, Rutledge, Stephens, Harris*) compared to three of Plaintiffs' selections (*Coughlin, DuBois, Thompson*). Other than in two Plaintiff-selected cases in which a treating physician (other than a prescriber) has been deposed, the parties have not yet taken any treating physician depositions and are working to schedule them in multiple cases.

In order to make informed and appropriate Trial Pool selections, the parties must be able to review the Mother and Minor Plaintiffs' medical records and other required discovery, depose the Mother Plaintiff and the Minor Plaintiff's father, and depose the key prescribing and treating physicians. In other words, the parties must be able to substantially complete the agreed-upon Discovery Group "Threshold Discovery" set forth in PTOs 15, 20, and 23.

As noted, the disparity in the progress of this Threshold Discovery between the Plaintiffs' Discovery Group cases and Defendants' stems primarily from two developments in the litigation. First, Plaintiffs dismissed 14 of Defendants' selections while retaining each of their 12 selections. While Plaintiffs have the right to voluntarily dismiss their cases, counsel for Defendants had repeatedly urged them to evaluate their cases and dismiss any they considered to be non-viable before the Discovery Group selection process last year so as to avoid the dismissals and delay that ultimately occurred. As a result of Plaintiffs' post-selection dismissals, each time Plaintiffs dismissed one of Defendants' Discovery Group selections, all of the discovery effort for that case became misdirected effort, since it no longer furthered the selection process, and Defendants had to select and begin a case anew. Moreover, of the 14

¹ For example, Plaintiffs have frequently identified additional key healthcare providers, such as OB/GYNs or mental healthcare providers, on the eve of depositions or at depositions.

dismissals, eight involved dismissals of selections that were themselves replacements of dismissed cases.² Second, the transition from Medical Records Consultants to RecordTrak as the designated records collection vendor effectively halted medical records collection from mid-January to mid-April 2014. Neither side anticipated that it would take more than two months to achieve this transition and begin collecting records again through RecordTrak, but both sides worked closely with RecordTrak to advance the process as quickly and smoothly as possible.³ This transition period exacerbated the records disparity between Plaintiffs' selections and Defendants' selections because many of Defendants' replacement cases were selected shortly before records collection was halted.

While these disparities are significant, they are correctable and indeed the parties have been working expeditiously. Depositions are being taken on a near daily basis, additional depositions have been scheduled, and RecordTrak is collecting records and making them available to Defendants. Defendants are eager to complete records collection and depositions and anticipate that a short extension of approximately six weeks to complete this discovery and select Trial Pool cases would remedy the disparity and allow the parties and the Court to make appropriate proposals and trial selections. Because of the November and December holidays, this short extension would move the trial date to right after the New Year, before any state court trial is scheduled to start.

² In fact, two lines of cases involved three replacements: 1) Defendants originally selected *Johnson* (12-2685), which was dismissed on April 25, 2013. *Johnson* was replaced by *Medlock* (13-968), which was dismissed on August 30, 2013. *Medlock* was replaced by *May* (12-237), which was dismissed on October 30, 2013. *May* was replaced by *Asphall* (13-4091) on November 1, 2013; 2) Defendants originally selected *Perkins* (13-1070), which was dismissed on May 30, 2013. *Perkins* was replaced by *Cutter* (13-157), which was dismissed on July 9, 2013. *Cutter* was replaced by *Breaux* (13-2291), which was dismissed on December 6, 2013. *Breaux* was replaced by *Fox* (12-7172) on December 27, 2013.

³ At the time the transition from Medical Record Consultants to RecordTrak was ordered, neither side had yet contracted with RecordTrak to provide collection services. Before RecordTrak would begin collecting records, complex issues of pricing, scope of work, and privacy protocols had to be negotiated.

2. **Threshold Discovery is Necessary to Select Representative Cases**

As the PSC has recognized, “[t]he hallmark of the bellwether process is that plaintiffs be representative of the multidistrict litigation as a group.” (Memorandum of Law in Support of Plaintiffs’ Steering Committee’s Motion to Amend Pretrial Order Nos. 39 and 44, 754-1.) However, the parties and the Court are less likely to select representative cases if the agreed-upon Threshold Discovery has not been substantially completed and there are significant discovery disparities between Plaintiffs’ Discovery Group cases and Defendants’ Discovery Group cases.

In particular, Defendants need to be able to take prescriber and other key healthcare provider depositions and do so with an adequate record of the Mother and Minor Plaintiffs’ medical history, which hinges, in many cases, on the collection of outstanding records by RecordTrak. Defendants are or will be working to schedule approximately 25 of the key prescriber and treating physician depositions across at least 13 of the Discovery Group cases and would expect to be able to schedule them to be completed by the end of May or first week in June.

These healthcare provider depositions are critical to identifying representative cases for multiple reasons, including:

- The ability to assess potential alternative causes, such as family history and genetics, other prescription medications, and other exposures. An evaluation of alternative causation is very important, and in most of these cases, there are significant potential alternative causes. Although birth defects occur for completely unknown reasons, a case where there are no alternative causation factors would not be a representative case.
- The ability to assess the Mother’s need for Zoloft, including her psychiatric symptoms, their severity and clinical presentation, and her course of treatment. Many of the cases involve Mother Plaintiffs with a history of depression and a continuing need for treatment with antidepressants, and it will be important to select cases representative of that population of women who have been prescribed Zoloft before or during pregnancy.

- The ability to assess the physician's prescribing practices for patients who are pregnant or seeking to become pregnant. Given Plaintiffs' claims that Pfizer failed to provide adequate warnings to physicians, a prescriber's practices regarding risk-benefit discussions when prescribing medications, his or her sources of information about risks and benefits, and whether any of these practices would have been different with any different or additional warning are all important pieces of information for both sides to consider in identifying representative and appropriate cases for the Trial Pool.
- The ability to assess the Minor Plaintiff's health, alleged injury, and prognosis. The cases involve a wide range of injuries of varying severity and prognosis. Cases in which the child has a unique or extremely severe injury would not be representative.

Under the current schedule, the parties are due to make Trial Pool selections by April 30, before many of these prescriber and other healthcare provider depositions will be able to be taken and records collected, primarily in Defendants' Discovery Group cases. Under this schedule, neither the parties, in making their selections, nor the Court, in evaluating such selections and choosing representative first case(s) to be tried, will have a meaningfully complete record. Not only would this be prejudicial to Defendants, but it also would undermine the reliability of the bellwether process. As the parties have already experienced, it can be challenging to schedule physician depositions even where both sides are, as they have been, committed to working around the doctors' busy schedules. A short extension of six weeks to complete these outstanding depositions would allow the parties to complete the process they have already begun in an orderly way, with substantial benefit to the parties and the Court.

3. A Short Extension Will Not Prejudice Plaintiffs

This MDL is less than two years old and has proceeded at a rapid pace. While delays are never desirable, a mere six to eight week extension is not prejudicial to Plaintiffs. Indeed, in its motion to amend Pretrial Order Nos. 39 and 44 to move up the date to select Trial Pool cases, the PSC asserted that the schedule did not provide sufficient time to prepare case-specific expert reports. (754-1.) However, the PSC's solution of accelerating the deadline to select the Trial Pool, which was partially adopted by the Court, merely shifted the burden of the already tight schedule.

The MDL remains the center of the Zolof litigation and the first trial will be here. With an extension, the parties will be able to complete the work-up they intended to achieve in the Discovery Group cases before making Trial Pool selections, and this Court will have additional time before it is to select cases for trial and additional information about the cases at the time it does so. Moreover, an extension will give the Court and the parties additional, much needed time to address outstanding discovery and evidentiary motions, including the *Daubert* motions. The modest extension Defendants request will allow those issues to be framed and resolved in a more organized and methodical fashion that will inform the ensuing preparation for trial.

Ultimately, for the bellwether process to succeed, it is more important that cases be carefully selected based on adequate information than that they be rushed to a trial date that was set before certain unexpected circumstances, such as the many Discovery Group dismissals and the records vendor change, occurred.

4. Defendants' Proposed Amended Schedule Should Be Adopted

For the reasons set forth above, Defendants request that the Court adopt the following amended schedule:

Deadline	Current Date	Requested Date
Designation of cases for the Trial Pool from the Initial Discovery Pool.	April 30, 2014	June 11, 2014
Parties to provide Court a list of the Trial Pool Cases, along with a short summary of each Plaintiff's Case.	May 5, 2014	June 16, 2014
Plaintiffs' additional non-causation expert reports and all case-specific expert reports for Trial Pool Cases shall be served.	May 30, 2014	July 11, 2014
Pfizer Defendants' additional generic non-causation expert reports and all case specific expert reports for Trial Pool Cases shall be served.	June 30, 2014	August 11, 2014
Generic and case specific expert discovery for Trial Pool Cases shall be completed.	August 15, 2014	September 26, 2014
<i>Daubert</i> motions and dispositive motions related to the Trial Pool Cases shall be due.	September 8, 2014	October 20, 2014
Responses to <i>Daubert</i> motions and dispositive motions related to the Trial Pool Cases shall be due.	September 22, 2014	November 3, 2014
Replies in support of <i>Daubert</i> motions and dispositive motions related to the Trial Pool Cases shall be due.	September 29, 2014	November 10, 2014
Motions in limine and motions concerning any documents as to which no agreement to admit has been reached shall be due.	October 14, 2014	November 25, 2014

Responses to motions in limine and motions concerning any documents as to which no agreement to admit has been reached shall be due.	October 20, 2014	December 1, 2014
Replies in support of motions in limine and motions concerning any documents as to which no agreement to admit has been reached shall be due.	October 27, 2014	December 8, 2014
Jury questionnaires distributed and jury selected.	October 28-29, 2014	December 9-10, 2014
Final pre-trial conference (including ruling on motions in limine and document issues, to the extent not reserved until trial).	October 30, 2014	December 11, 2014
First trial begins; opening statements and start of testimony.	November 3, 2014	January 7, 2015
Trial testimony continues.	November 4-10, 2014	January 8-14, 2015
Trial testimony continues.	November 11-21, 2014	January 15-27, 2015
Closing arguments and jury instructions; start of jury deliberations.	November 24, 2014	January 28, 2015
Jury deliberations continue.	November 25, 2014	January 29, 2015

CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court amend the schedule set forth through PTOs 39, 44, and 56 and extend the trial schedule as set forth above and in the accompanying Proposed Order.

Dated: New York, New York
April 24, 2014

Respectfully submitted,

/s/ Mark S. Cheffo

Mark S. Cheffo

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*Attorneys for Defendants Pfizer Inc.,
including its former division J.B. Roerig &
Co., Pfizer International LLC, and
Greenstone LLC*

CERTIFICATE OF SERVICE

I hereby certify that on April 24, 2014, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which shall send electronic notification of such filing to all CM/ECF participants.

Dated: New York, New York
April 24, 2014

/s/ Mark S. Cheffo

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EASTERN DISTRICT OF PENNSYLVANIA**

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**[PROPOSED] ORDER GRANTING
DEFENDANTS' MOTION TO AMEND PRETRIAL ORDER NOS. 39, 44, AND 56 TO
EXTEND TRIAL SCHEDULE**

AND NOW, on this ____ day of April, 2014, upon consideration of Defendants' Motion to Amend Pretrial Order Nos. 39, 44, and 56 to Extend Trial Schedule, it is hereby **ORDERED** that the Motion is **GRANTED**. Further, it is hereby **ORDERED** that the following schedule is established:

Deadline	Date
Designation of cases for the Trial Pool from the Initial Discovery Pool.	June 11, 2014
Parties to provide Court a list of the Trial Pool Cases, along with a short summary of each Plaintiff's Case.	June 16, 2014
Plaintiffs' additional non-causation expert reports and all case-specific expert reports for Trial Pool Cases shall be served.	July 11, 2014
Pfizer Defendants' additional generic non-causation expert reports and all case specific expert reports for Trial Pool Cases shall be served.	August 11, 2014

Generic and case specific expert discovery for Trial Pool Cases shall be completed.	September 26, 2014
<i>Daubert</i> motions and dispositive motions related to the Trial Pool Cases shall be due.	October 20, 2014
Responses to <i>Daubert</i> motions and dispositive motions related to the Trial Pool Cases shall be due.	November 3, 2014
Replies in support of <i>Daubert</i> motions and dispositive motions related to the Trial Pool Cases shall be due.	November 10, 2014
Motions in limine and motions concerning any documents as to which no agreement to admit has been reached shall be due.	November 25, 2014
Responses to motions in limine and motions concerning any documents as to which no agreement to admit has been reached shall be due.	December 1, 2014
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Trial testimony continues.	January 15-27, 2015
Closing arguments and jury instructions; start of jury deliberations.	January 28, 2015
Jury deliberations continue.	January 29, 2015

Dated: April ____, 2014

SO ORDERED

Hon. Cynthia M. Rufe

CERTIFICATE OF SERVICE

I hereby certify that on April 24, 2014, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which shall send electronic notification of such filing to all CM/ECF participants.

Dated: New York, New York
April 24, 2014

/s/ Mark S. Cheffo